DEPARTMENT OF HEALTH & HUMAN SERVICES
Food and Drug Administration
New England District

q2099d

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December 12, 2001

WARNING LETTER

NWE-07-02W

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Darrell L. Tobin, President
Tobin Farms Velvet Antler
106 Hughes Road-P.O. Box 529
Mapleton, ME 04757

Dear Mr. Tobin:

The Food and Drug Administration (FDA) recently completed a review of labeling for your products, Velvet Antler and Electric Essence.

We have determined that your product, Velvet Antler, is misbranded under Section 403(r)(1)(B) of the Federal Food, Drug, and Cosmetic Act (the Act) and the Food Labeling Regulations in Title 21, Code of Federal Regulations, Part 101 (21 CFR 101), as explained below. We also have determined that your products, Velvet Antler and Electric Essence, are drugs under Section 201(g) of the Act.

The product, Velvet Antler, is labeled as a dietary supplement and with the claim "To Promote Wellness & Vitality!" This claim is subject to the requirements of Section 403(r)(6) of the Act. A claim made under the authority of that Section must include the disclaimer set forth in Paragraph (C) of that Section. FDA regulations (21 CFR 101.93(b)-(e)) require that the disclaimer appear on each label panel that bears a claim pursuant to Section 403(r)(6) of the Act and that, if the disclaimer is not adjacent to the claim, it must be linked to the claim with a symbol and be set off in a box. If the claim does not include the mandatory disclaimer, then the product is a drug under Section 201(g)(1)(C) of the Act. This issue is discussed in detail in the preamble to the January 6, 2000 final rule, "Regulations on Statements Made for Dietary Supplements Concerning the Effect of the Product on the Structure or Function of the Body" [(65 FR 1000): Refer to Section III, Legal Authority, A.1. (95.), page 1033].

The Velvet Antler label does include a statement, "Although the FDA does accept that velvet antler causes no harm, it has not been evaluated by the FDA and cannot claim to diagnose, treat, cure or prevent." However, the text and placement of the statement does not comply with the disclaimer requirements of Section 403(r)(6)(C) of the Act and 21 CFR 101.93(c)-(d). The statement also is false and misleading under Section 502(a) of the Act. FDA has not evaluated the safety of Velvet Antler and has not determined that the product "causes no harm."

Velvet Antler, if marketed as a dietary supplement, is in violation of other food labeling provisions of the Act as follows:

1. The label for Velvet Antler does not bear mandatory nutrition labeling (i.e., supplement facts label) required for dietary supplements (21 CFR 101.36). The product is not eligible for the small business exemption from nutrition labeling requirements because the product makes structure/function claims. (Section 403(q)(5)(E)(i)(I) of the Act).

2. The Velvet Antler product is contained in a capsule, but the capsule ingredients are not declared on the label as required by 21 CFR 101.4 and Section 403(i)(2) of the Act.

Promotional material accompanying your Velvet Antler product is labeling, as defined in Section 201(m) of the Act, and include: "Good Health To You From 'Dean' And The Gang*" pamphlets, "Velvet Antler: Science Substantiates New Hope for Arthritis Sufferers" article reprints, and various testimonial. These materials include the following, and other, therapeutic claims:

1. **"Good Health To You From 'Dean' And The Gang*"** - "...strengthen the body's defense against illness... use of more traditional methods and treatment of disease and illness... macrobiotic approach to cancer treatment as an alternative to chemotherapy... suppress a specific ailment... relieve join pain...," reference to the book "The Arthritis Cure," and "...anti-ulcer effect... showed significant improvements in parameters normally associated with senility... liver damage caused by free radicals could be alleviated... aided recovery from cervical injuries... hypotensive/cardiovascular effects... accelerated recovery from injuries... can reduce incidence of influenza and acute respiratory disease ..."

2. **"Velvet Antler: Science Substantiates New Hope for Arthritis Sufferers"** - "...could be the most significant breakthrough for arthritis sufferers... velvet antler has reportedly been used to prevent, heal and relieve ailments and injuries...," "Osteo-Arthritis Breakthrough... prove that velvet antler is a significant anti-inflammatory agent for the symptoms of osteo-arthritis and possibly other types of acute chronic inflammation as well...chronic joint pain of osteo-arthritis, the side effects of chemotherapy... joint restoration... Studies on mice have shown anti-tumor activity in velvet antler... reducing the blood's tendency to clot, decreasing risk of stroke..."

3. **"Read what people are saying about the benefits of Tobin Farms™ Velvet Antler..."** - "Joint Stiffness...Because my knees don't hurt now...I stopped (capsules) for one week and the pain returned...Joint pain gone!...I take it for achy hands and joints. My hands are no longer stiff in the morning...Blood Pressure Normal, Hip Pain Gone...I had bad hip joint problems, carpal tunnel...blood pressure had gone up...with (Tobin Farms) Velvet Antler, it had gone back to normal...Knee Surgery Avoided...Varicose veins...It was painful to walk in the mornings. But there is no problem now that I take (Tobin Farms) Velvet Antler...Able To Toss Hay Without Shoulder Pain...Carpal Tunnel...Relieved...I have carpal tunnel in both hands (and wrists). I would wake up at night with fingers bent, locked, pain and tingling...acute rheumatoid arthritis...suffered from arthritis...suffering from Multiple Sclerosis...has been taking velvet deer antler, she has not suffered a single multiple sclerosis attack;"

4. **"John Francis McDermott"** testimonial - "... I HAD TORN THE ROTATOR CUFF IN MY LEFT SHOULDER ... MY SHOULDER IS 95% OK AND NO SURGERY. A PROBLEM WITH MY BACK WAS HANDLED IN THE SAME MANNER WITH THE SAME RESULTS ... MY DAUGHTER SUFFERS FROM MIGRAINES. SHE TOOK THE VELVET ANTLER CAPSULES AND HAS NOT EXPERIENCED ONE ATTACK. HER FRIEND GRANT, WHO SUFFERS FROM MIGRAINES, TRIED THEM AND FOUND RELIEF. ANOTHER FRIEND, SUSAN, FOUND RELIEF FOR ARTHRITIC PAIN AND SWELLING;" and

5. **"Jack Reed"** testimonial - "...initial signs of arthritis...The stiffness and pain in my neck is 100% gone...It has corrected a neck problem that I have been troubled with..."

These claims cause your Velvet Antler product to be a drug as defined in Section 201(g) of the Act. Because we are unaware of any evidence that this product is generally recognized as safe and effective when used as labeled, it also is a new drug as defined under Section 201(p) of the Act. Under Section 505 of the Act, a new drug may not be legally marketed in the United States without an approved New Drug Application (NDA).

The Velvet Antler product is further misbranded under Section 502(f)(1) of the Act, in that it fails to bear adequate directions for use, and under Section 502(a), in that the labeling is false and misleading because it suggests that the product is safe and effective for its intended use, although this has not been established.

Your Electric Essence product is accompanied by a three-page information sheet titled "TOBIN FARMS "Electric Essence"™." The information sheet, which is labeling as defined in Section 201(m) of the Act, includes the following, and other, therapeutic claims and directions for use for the Electric Essence product:

"... to stop bleeding when applied topically to wounds...is a coagulant acting with the, naturally occurring, vitamin K in blood. It will cause instant coagulation in any

wound...SUGGESTED DOSAGE: Apply liberally to open wounds to stop bleeding...A Naturally Occurring Antibiotic...TOPICAL USES... 1. Burns... 7. Infections...ORAL USES... 1. All internal infections a. Any bacteria b. Any virus c. Any fungus ... * 4. Blood in stool... * 12. Hantavirus... * 13. Anthrax... *20. Ear infections..."

"* 4 **Blood in stool**. This product will turn your stool black if you are passing blood in the G.I. tract in any amount even when a tab stool analysis shows analysis shows negative blood. Continue to take this product and it will clear up. Continue for 60 days after your stool returns to normal color (normally) in 10 – 20 days.)"

"* 13. **Anthrax**. (biological warfare agent). Anthrax is a virus. It is deadly. If there is ever a threat of an anthrax release in this country, take 10 drops twice daily as preventative. For people with anthrax, take 30 drops 3 times daily for 30 days then 10 drops twice daily for 90 days.

"* 20. **Ear infection**. If the ear infection is extreme, the infection may have deteriorated the ear drum. "Electric Essence"™ will kill the infection but the weakened eardrum may rupture. The eardrum would probably have burst anyway. It will heal itself and hearing will be restored when the infection is eliminated. Stop all dairy products. Apply into ear canal 3 drops once daily for 3 days."

These claims cause the Electric Essence product to be a drug as defined under Section 201(g) of the Act. Further, because we are unaware of any evidence that this product is generally recognized as safe and effective for use as labeled, it is a new drug under Section 201(p) of the Act. Therefore, it may not be legally marketed in the United States without an approved NDA, as required in Section 505 of the Act.

The Electric Essence product is further misbranded under Section 502(f)(1) of the Act, in that it fails to bear adequate directions for use, and under Section 502(a), in that the labeling is false and misleading because it suggests that the product is safe and effective for its intended use, although this has not been established.

If you intend to market the Electric Essence product as a dietary supplement, it must meet the requirements for a dietary supplement, as defined in Section 201(ff) of the Act and must comply with the Food Labeling Regulations in 21 CFR 101. Section 201(ff)(2)(A) defines dietary supplement as a product that is intended for ingestion. This does **not** include external/topical products; mouthwashes, rinses; or nasal/inhaled products (US v. Ten Cartons, Ener-B Nasal Gel, 888 F. Supp. 381, 393-94 (E.D.N.Y.), aff'd, 72 F.3d 285 (2d Cir. 1995)).

This letter is not intended to be an all-inclusive list of deficiencies in your labeling. It is your responsibility to ensure adherence to each requirement of the Act and applicable regulations. You should review all labels and labeling of your products to ensure that they comply with the Act and applicable regulations.

You should know that these serious violations of the law could result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to, seizure and/or obtaining a court injunction against further marketing of your products.

It is necessary for you to take immediate action to correct these deficiencies. You should let this office know in writing within fifteen (15) working days from the date you receive this letter what steps you have taken to correct the violations. For corrections that you cannot complete within the fifteen (15) working days, state the reason for the delay and your timeframe for completion. We also ask that you provide documentation of the corrections as they are made, including copies of revised labels, and that you explain your plan for preventing these violations in the future.

Your reply should be sent to Patricia Murphy, Compliance Officer, U.S. Food and Drug Administration, One Montvale Avenue, 4th Floor, Stoneham, MA 02180. If you have any questions concerning this matter, please contact Patricia Murphy at 781-596-7758.

Sincerely,

Gail T. Costello
District Director
New England District Office